DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg 20-Denver Federal Center
P O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone 303-236-3000
FAX 303-236-3100

December 2, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. P. Gordon Levy, CEO
Navajo Manufacturing Company, Inc.
5330 Fox Street,
Denver, Colorado 80216

Ref. # DEN- 03-07

Dear Mr. Levy:

On July 8 through 10, 2002, the Food and Drug Administration (FDA) conducted an inspection of your OTC pharmaceutical relabeling operation located at 601 W. 50th St., Denver, CO. During the inspection, FDA Investigator Patricia A. Cortez documented significant deviations from the Current Good Manufacturing Practice (cCGMP) for Finished Pharmaceuticals regulations (Title 21, Code of Federal Regulations (C.F.R.), Parts 210 and 211). These deviations cause the drug products relabeled by your firm to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 351(a)(2)(B). These deviations include, but are not limited to, the following:

1) Failure to establish an adequate quality control unit (QCU) that has the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products. The responsibilities and procedures applicable to the quality control unit should be in writing and should be followed [21 C.F.R. §§ 211.22(a) and 211.22(d)].

   For example, your firm failed to establish a QCU. Consequently, none of the functions required of a QCU are accomplished, including approving written procedures, reviewing processing and control records, releasing/rejecting components, labels, and finished products.

2) Failure to assure that each person engaged in the manufacture, processing, packing, or holding of a drug product has the appropriate education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training should be in the particular operations that the employee performs and in current good manufacturing practice (including the CGMP regulations) as they relate to the employee's functions [21 C.F.R. § 211.25(a)].

   For example, the firm fails to conduct any GCMP training for its employees or supervisors involved in the relabeling for their drug products.

3) Failure to have written procedures for the entire operation. This includes Standard Operating Procedures (SOPs) that are critical for a relabeling operation:

   - Failure to establish written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials [21 C.F.R. § 211.122(a)].

   - Failure to maintain strict controls over labeling issued for use in drug product labeling operations. Procedures shall be written describing in sufficient detail the control procedures employed for the issuance of labeling [21 C.F.R. §§ 211.125(a) and 211.125(f)].

   - Failure to establish adequate written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products [21 C.F.R. § 211.130].

   - Failure to establish adequate written procedures describing the handling of all written and oral complaints regarding a drug product and to maintain a written record of each complaint [21 C.F.R. §§ 211.198(a) and 211.198(b)].

4) Failure to assure packaged and labeled products are examined during finishing operations to assure that containers and packages have the correct label and that results of examination are recorded in the batch production or control records [21 C.F.R. §§ 211.134(a) and 211.134(c)].

   For example, the firm failed to examine finished relabeled products and then document the product examination.

5) Failure to maintain a written record of major equipment cleaning and maintenance [21 C.F.R. § 211.182].

   For example, the firm fails to maintain equipment cleaning and use logs for equipment used in the relabeling of drug products.

6) Failure to establish adequate master and batch production and control records for each relabeled drug product. [21 C.F.R. §§ 211 186 and 211.188].

For example, your firm did not have any master or batch production records to document the performance of relabeling operations.

The above list of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with the requirements of the CGMP regulations. Federal agencies are advised of the issuance of all warning letters so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice.

We acknowledge receipt of your response to the FDA-483, dated July 10, 2002. We consider your response to be seriously inadequate because it does not specify what corrections your firm will make and it gives no timeframes for when any corrections will be implemented.

Please advise this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have or will take to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframes within which the corrections will be completed. Your response should be directed to H. Tom Warwick, Compliance Officer, at the address on the letterhead.

Sincerely,

B. Belinda Collins
District Director